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Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

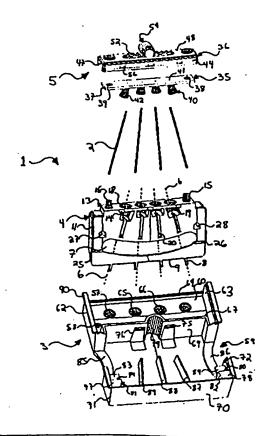
(88) Date of publication of the international search report:

4 June 1998 (04.06.98)

(54) Title: IMMUNOASSAYS IN CAPILLARY TUBES

(57) Abstract

A fluorescent immunoassay employing the interior surface of a capillary tube is provided. Devices to permit immunoassays using one or more capillary tubes, an apparatus for use with the devices, and a process for screening for analyte in a sample using the devices and apparatus are also provided. Samples suspected of containing analyte are added to a disposable self-contained sample tray containing one or more sample wells, mixed with a reagent, drawn into one or more spacedapart capillary tubes held within a disposable cartridge connected to an analytical apparatus, reacted with a binding member on the surface of the capillary tube, washed to stop the reaction, and dried by the apparatus. The capillary tube is then exposed to a signal generation device to create a fluorescence signal that is detected using a signal detector. The apparatus determines the presence of the analyte and optionally determines the amount of analyte present in the sample, and presents the results to the operator.



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Int. .ilonal Application No PCT/US 97/12737

A CLASSIFICATION OF SUBJECT MATTER
IPC 6 G01N33/543 B01L9/06 G01N33/552 B01L3/00 G01N35/04 G01N21/03 //G01N33/94,G01N33/04 According to International Patent Classification (IPC) or to both national classification and IPC B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 6 BO1L GO1N Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used) C. DOCUMENTS CONSIDERED TO BE RELEVANT Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. X WO 95 21382 A (FIELDS ROBERT E) 10 August 1-4,8,9, 1995 45 A see abstract; figures 20,35, 46,47 see page 15, line 18 - line 24 X EP 0 320 385 A (MELET SCHLOESING LAB) 14 1.9 June 1989 see abstract; figure 1 6,23,35, 45,46 1,9,20, 21,27,46 US 4 116 638 A (KENOFF MICHAEL B) 26 X September 1978 see the whole document 23,35 -/--Patent family members are listed in annex. Further documents are listed in the continuation of box C. X * Special categories of cited documents : "I" later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such docu-*O" document referring to an oral disclosure, use, exhibition or ments, such combination being obvious to a person skilled in the art. document published prior to the international filing date but later than the priority date claimed "&" document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report 2 0. 04. 98 30 March 1998 Name and mailing address of the ISA Authorized offices European Patent Office, P.B. 5818 Patentiaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nt, Fax: (+31-70) 340-3016 Ceder, 0

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Form PCT/ISA/210 (continuation of second sheet) (July 1992)

Information on patent family members

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PCT/US 97/12737

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)
This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
Claims Nos.: because they relate to parts of the international Application that do not comply with the prescribed requirements to such an extent that no meaningful international Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a). Box II Observations where unity of invention is backed (Continue) to a 4 they 0 and the second and third sentences of Rule 6.4(a).
Continuation of them 2 of tirst sheet)
This International Searching Authority found multiple inventions in this international application, as follows: See further information
As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which lees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark on Protest The additional search fees were accompanied by the applicant's protest. X No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

- 1. Claims: 1-19; 31-34; 45(partly)

 An (semi-)automated apparatus for screening an analyte in a sample, with a cartridge for holding a plurality of spaced-apart capillary tubes, and a tray for holding multiple portions of a sample.
- 2. Claims: 20-30; 46-64; 45(partly)
 A process to analyse an analyte in a sample by a fluorescently-labelledconjugate binding-assay in a capillary tube, said capillary tube being at
 least partly coated on its inner surface with a substrate capable of
 binding to a fluorescently-labelled conjugate, on at least portion of its
 interior surface and a process for preparing a glass capillary tube.

Information on patent family members

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